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10/584,968	06/30/2006	Aaron Kaplan	ANVIL.001BNP1	9697

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EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,968	KAPLAN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/19/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24 and 30-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24 and 30-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/27/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/03/2007, 04/26/2007, 05/30/2007, 07/17/2007, 09/18/2007, 03/21/2008, 03/27/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. For examination purposes frond is being interpreted as being any extension that is protruding from the proximal or distal portion of the stent. Additionally, the frond is a segment which can be between two rings at the distal or proximal portion of the stent.

Claim Objections

2. Claims 30-35, 45, and 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 30-33 are identical to claims 16-19, respectively.

Claims 34 and 35 are identical to claims 23 and 24, respectively.

Claims 45 and 46 are identical to claims 21 and 22, respectively.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 14, 15, 20-22, and 36-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-18 of copending Application No. 11/744,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves an identical structure.

The claim limitations of claim 14 are found in the combination of claims 1 and 8 of Application 11/744,812.

With respect to claims 15 and 20-22, these limitations are found in claims 15-18 of the Application 11/744,812.

With respect to claims 36-46, these limitations are found in claims 8-18 of the Application 11/744,812.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 14, 15, 20-22, 45, and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-18 of copending Application No. 11/744,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves an identical structure.

The claim limitations of claim 14 are found in the combination of claims 1 and 10 of Application 11/744,802.

With respect to claims 15 and 20-22, these limitations are found in claims 17-20 of the Application 11/744,802.

With respect to claims 45 and 46, these limitations are found in claims 19 and 20 of the Application 11/744,802, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 48 and 49, introduce a "laminate structure" which has no support in the written disclosure.

When treating the limitations of claim 48 and 49 for rest of the office action, the "laminate structure" will be interpreted as a coating layer.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 14, 16, 20, 23, 24, 30, 34-36, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Vardi et al. (6,325,826).

Vardi discloses the following claimed limitations:

Claim 14: A prosthesis for placement at an opening from a main body lumen (8) to a branch body lumen (7), the prosthesis comprising: a radially expansible support (15), the support configured to be deployed in at least a portion of the branch body lumen (Fig. 6c-6g); at least one frond (18) extending from an end of the support (15) (the fronds are located a the proximal end (30) Fig. 5 -6g) and configured to be positioned across the Os and into the main body lumen (Fig. 6c-6g); and at least one circumferential link (34) connected to the frond (18), the circumferential link spaced axially apart from the support (Fig. 5 and Col. 7 Lines 45-47). The circumferential link

can be placed at any location near or apart from the support since it is a movable link that is used to hold the fronds before deployment.

Claims 16 and 30: That the at least one frond (18) includes at least three fronds (Fig. 5-6g).

Claims 20 and 44: That the support (15) is on a first end of the frond (18) (the proximal end of the support 15 is connected to the distal end of the frond Fig. 5 and 6g), and the circumferential link (34) is on a second end of the frond (18) (the link is movable therefore it can be placed at the proximal end of the fronds which would be the second end).

Claims 23 and 34: The prosthesis comprising an endothelial cell ingrowth surface (Fig. 5-6g). The surface is capable of promoting cell ingrowth.

Claims 24 and 35: The prosthesis comprising a non thrombogenic surface (Fig. 5-6g). The surface is capable of preventing thrombosis since the device is design to prevent the drawbacks from previous device that caused thrombosis (Col. 1 Lines 40-48).

Claim 36: That at least one frond (18) comprises a plurality of fronds (Fig. 5-6g) and wherein the circumferential link (34) connects to each of the plurality of fronds (18) (Fig. 5 and Col. 7 Lines 45-47).

10. Claims 14, 15, 20-22, 36-41, 43-46, 48, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Callol et al. (2002/0183763).

Callol discloses the following claimed limitations:

Claim 14: A prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (26), the

support configured to be deployed in at least a portion of the branch body lumen ([0140] last sentence); at least one frond (39 see the figure on page 7 of this document) extending from an end of the support (26) (the fronds are located a the distal end seen in the figure in page 7 of this document) and configured to be positioned across the Os and into the main body lumen (Fig. 40-41); and at least one circumferential link (28) connected to the frond (39), the circumferential link spaced axially apart from the support (Fig. 19 and [0146]).

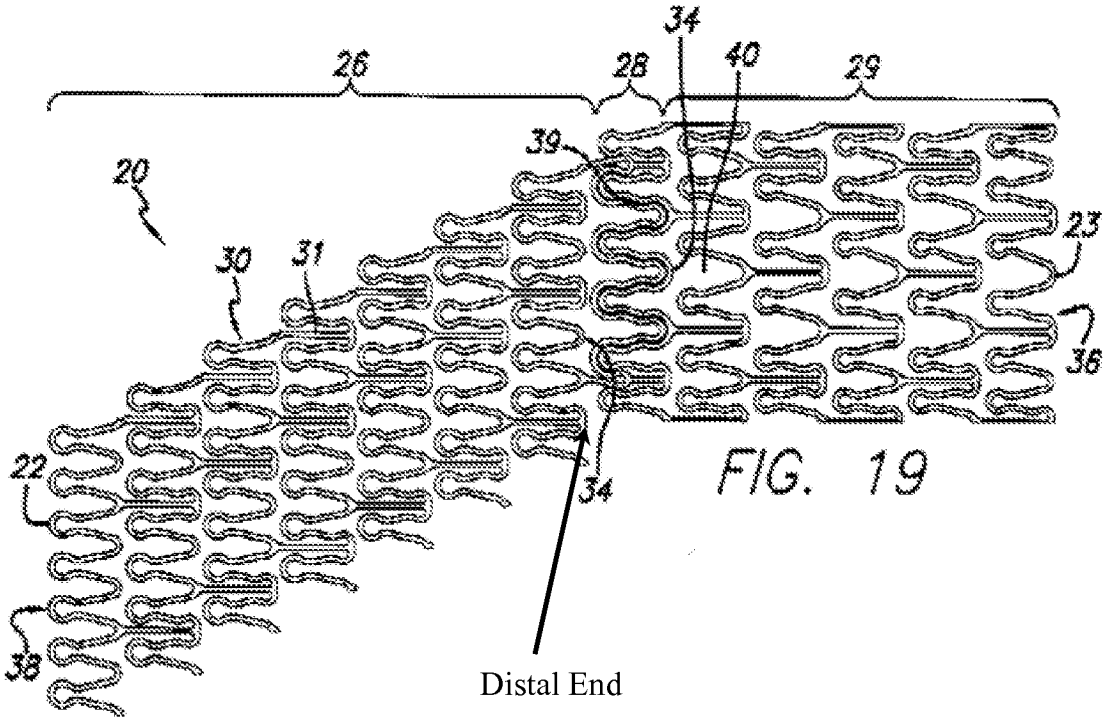

FIG. 19

Claims 15 and 43: That the circumferential link (28) is expandable from a first, reduced diameter (the diameter that the link has before it is deployed into the vessel) to a

second, enlarged diameter (the diameter of the deployed link where it expands to match the diameter of the vessel as seen in Fig. 40-41).

Claims 20 and 44: That the support (26) is on a first end of the frond (39) (the distal end of the support 26 is connected to the proximal end of the frond as seen in the figure in page 7 of this document), and the circumferential link (28) is on a second end of the frond (39) (Fig. 19).

Claims 21 and 45: That the circumferential link (28) is radiopaque ([0148] first sentence). The link (28) is made from a ring (30) and strut (31) which can have variable thicknesses that provide higher radiopacity therefore they are radiopaque.

Claims 22 and 46: That the circumferential link (28) has a greater radiopacity than the frond (39). The radiopacity of the link (39) as disclosed in paragraph [0152] varies depending on the thickness of the ring (30) and the strut (31) therefore the link is capable of having higher radiopacity than the frond. Furthermore, the frond (39) is not radiopaque which indicates that the link will have higher radiopacity than the frond.

Claim 36: That at least one frond (39) comprises a plurality of fronds (Fig. 19 where each frond is the distal point of the sinusoidal wave which is formed by connecting all the fronds (39) together) and wherein the circumferential link (28) connects to each of the plurality of fronds (39) (Fig. 19 and [0146]).

Claim 37: That at least a portion of the radially expansible support (26) comprises a drug coating ([0150] Lines 1-2), and at least a portion of the fronds(39) and the circumferential link (28) are without a drug coating (Claim 20). It is disclosed that the

device can be coated completely or only portions which indicates that the fronds and link are not coated.

Claim 38: That the drug coating is configured to produce a controlled drug release rate ([0150] Lines 9-11).

Claim 39: That the drug is one of an anti-cell prolifertive ([0150] Lines 18-19), anti cell migration, anti-neo plastic, anti inflammatory drug ([0150]).

Claim 40: That the drug is configured to reduce an incidence or amount of restensosis ([0150] Lines 1-4).

Claim 41: That the drug coating includes a first coating and a second coating ([0150] Lines 4-11).

Claim 48: That the prosthesis includes a laminate structure (a layer used for adherence of the drug to the coating) and a drug incorporated into the laminate structure ([0150] Lines 1-11).

Claim 49: That the laminate structure includes a base layer and a top layer (a first and second coating), the drug being incorporated into at least one of the top layer and the base layer ([0150] Lines 4-11).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 17, 18, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (6,325,826) in view of Liu et al. (2004/0143209).

Vardi teaches all the claimed limitations discussed above however, Vardi does not disclose that the fronds comprises a helical configuration.

Liu discloses that the frond of a stent can have a helical configuration (Fig. 2 and [0007] and [0011]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Vardi with fronds having a helical shape in view of the teachings of Liu, in order to have the fronds self-anchor to the main vessel and stent.

13. Claims 14, 19, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers et al. (5,342,387) in view of Vardi et al. (6,325,826).

Claim 14:

Summers discloses a prosthesis for placement at an opening from a main body lumen to a branch body lumen (Fig. 9), the prosthesis comprising: a radially expansible support (144, 146), the support configured to be deployed in at least a portion of the branch body lumen (Fig. 9); at least one frond (Col. 6 Lines 58-62) extending from an end of the support (144, 146) (Fig. 12) and configured to be positioned across the Os and into the main body lumen (Fig. 9 and Col. 6 Lines 50-57).

Summers teaches all the claimed limitations discussed above however, Summers does not disclose a circumferential link connected to the fronds.

Vardi discloses that at least one circumferential link (34) connected to the frond (18), the circumferential link spaced axially apart from the support (Fig. 5 and Col. 7 Lines 45-47). The circumferential link can be placed at any location near or apart from the support since it is a movable link that is used to hold the fronds before deployment.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Summers with a circumferential link in view of the teachings of Vardi, in order to hold the fronds in a collapsed position to avoid misplacement of the prosthesis as well as false deployment which can cause damage to the vessel wall.

Claims 19 and 33: Summer discloses that at least a portion of the at least one frond comprises a lubricous coating (Col. 4 Lines 27-30). The surface of the stent (this includes the fronds) is coated with a gel coating which causes the surface to be smooth (Col. 4 Lines 36-40).

14. Claims 42, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (2002/0183763) in view of Jang (2004/0106985).

Claim 42:

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate.

Jang discloses that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate ([0351]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with different release rates for the drug coatings in view of the teachings of Jang, in order to control the amount of drug that is released as well as to better enable safe encapsulation of the implanted stent.

Claims 50 and 51:

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the prosthesis includes one or more reservoirs configured to be loaded with one or more drugs.

Jang discloses that the prosthesis includes one or more reservoirs (27) configured to be loaded with one or more drugs ([0352] first sentence).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with reservoirs for loading one or more drugs in view of the teachings of Jang, in order to facilitate the retention and delivery of the drugs.

15. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (2002/0183763) in view of Rudakov et al. (6,451,050).

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the prosthesis includes a drug incorporated into a polymer matrix.

Rudakov discloses that the prosthesis includes a drug incorporated into a polymer matrix (Col. 4 Lines 41-43).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with drug incorporated to a polymer matrix in

view of the teachings of Rudakov, in order to incorporate the drug into the stent which is well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773